

WHAT IS CLAIMED IS:

1. An isolated *Chlamydia* species HMW protein wherein the apparent molecular weight is about 105-115 kDa, as determined by SDS-PAGE, or a fragment or analogue thereof.
2. The protein of claim 1 which is substantially purified.
3. The protein of claim 1 wherein the *Chlamydia* species is *Chlamydia trachomatis*, *Chlamydia pecorum*, *Chlamydia psittaci* or *Chlamydia pneumoniae*.
4. The protein of claim 1 having an amino acid sequence shown in SEQ ID No.: 2, 15 or 16 or a fragment or conservatively substituted analogue thereof.
5. The fragment of claim 4, having an amino acid sequence shown in SEQ ID No.: 3, 17 or 25-37.
6. The protein of claim 1 recognizable by an antibody preparation that specifically binds to a peptide having an amino acid sequence of SEQ ID No.: 2, 15 or 16 or a fragment or conservatively substituted analogue thereof.
7. An isolated nucleic acid molecule encoding the HMW protein of claim 1 or a fragment or an analogue thereof.
8. The nucleic acid molecule of claim 7 wherein the *Chlamydia* species is *Chlamydia trachomatis*, *Chlamydia pecorum*, *Chlamydia psittaci* or *Chlamydia pneumoniae*.
9. The nucleic acid molecule of claim 7 wherein the encoded protein has the amino acid sequence of SEQ ID No: 2, 15 or 16 or a fragment or conservatively substituted analogue thereof.

10. An isolated nucleic acid molecule having a sequence selected from the group consisting of:

- a) a DNA sequence of SEQ ID No.: 1, 23 or 24, or a complementary sequence or fragment thereof;
- b) a DNA sequence encoding a HMW protein having the amino acid sequence of SEQ ID No.: 2, 15 or 16 or fragment thereof;
- c) a DNA sequence encoding a deduced amino acid sequence of SEQ ID No.: 2, 15 or 16 or the complimentary or degenerate sequence thereto or fragment thereof; and
- d) a nucleic acid sequence which hybridizes under stringent conditions to any one of the sequences defined in a), b) or c).

11. A recombinant expression vector adapted for transformation of a host comprising the nucleic acid molecule of claim 7 or 10.

12. A recombinant expression vector adapted for transformation of a host comprising the nucleic acid molecule of claim 7 or 10 and expression means operatively coupled to the nucleic acid molecule for expression by the host of HMW protein or a fragment or analogue thereof.

13. The expression vector of claim 12, wherein the expression means includes a nucleic acid portion encoding a leader sequence for secretion from the host of the HMW protein or a fragment or analogue thereof.

14. A transformed host cell containing an expression vector of claim 12.

15. A transformed host cell containing an expression vector of claim 13.

16. An isolated recombinant protein or fragment or analogue thereof producible by the transformed host of claim 14.

5 17. An isolated recombinant protein or fragment or analogue thereof producible by the transformed host of claim 15.

18. A recombinant vector for delivery of a HMW protein or fragment or analogue thereof to a host comprising the nucleic acid molecule of claim 7 or 10.

19. An immunogenic composition, comprising at least one component selected from the group consisting of:

- 15 a) an isolated HMW protein, wherein the apparent molecular weight is about 105-115 kDa, as determined by SDS-PAGE, or a fragment or conservatively substituted analogue thereof;
- 20 b) an isolated nucleic acid molecule encoding a HMW protein of a) or a fragment or analogue thereof;
- 25 c) an isolated nucleic acid molecule having the sequence of SEQ ID No. 1, 23 or 24, the complimentary sequence thereto or a nucleic acid sequence which hybridizes under stringent conditions thereto or fragment thereof;
- 30 d) an isolated recombinant protein or fragment or analogue thereof producible in a transformed host comprising an expression vector comprising a nucleic acid molecule as defined in b) or c) and expression means operatively coupled to the nucleic acid molecule for expression by the host of said HMW protein or the fragment or analogue thereof;
- 35 e) a recombinant vector comprising a nucleic acid sequence of b) or c) encoding a HMW protein or fragment or analogue thereof; and

1) a transformed cell comprising the vector of e),
and optionally an adjuvant, and a pharmaceutically acceptable carrier or diluent therefor, said composition producing an
5 immune response when administered to a host.

20. An antigenic composition, comprising at least one component selected from the group consisting of:

- 10 a) an isolated HMW protein, wherein the apparent molecular weight is about 105-115 kDa as determined by SDS-PAGE, or a fragment or analogue thereof;
- 15 b) an isolated nucleic acid molecule encoding a HMW protein of a), or a fragment or analogue thereof;
- 20 c) an isolated nucleic acid molecule having the sequence of SEQ ID No.: 1, 22, 23 or 24, the complimentary or degenerate sequence thereto or a nucleic acid sequence which hybridizes under stringent conditions thereto;
- 25 d) an isolated recombinant protein or fragment or analogue thereof producible in a transformed host comprising an expression vector comprising a nucleic acid molecule as defined in b) or c) and expression means operatively coupled to the nucleic acid molecule for expression by the host of said HMW protein or the fragment or analogue thereof;
- 30 e) a recombinant vector, comprising a nucleic acid sequence of b) or c) encoding a HMW protein or fragment or analogue thereof; and
- f) a transformed cell comprising the vector of e),

and optionally an adjuvant, said composition producing an
35 immune response when administered to a host.

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21. A method of producing an immune response in an animal comprising administering to said animal an effective amount of the antigenic composition of claim 20 or the immunogenic composition of claim 19.

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22. The method of claim 21 wherein the animal is a mammal or a bird.

23. Antisera raised against the antigenic composition of claim 20 or the immunogenic composition of claim 19.

24. Antibodies present in the antisera of claim 23 that specifically bind a HMW protein or a fragment or analogue thereof.

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25. A diagnostic reagent selected from the group consisting of: the protein of claim 1, the nucleic acid molecule of claim 10, the immunogenic composition of claim 20, the antigenic composition of claim 19, the antisera of claim 23, the vector of claim 12, the transformed cell of claim 14, and the antibodies of claim 24.

26. A method for detecting anti-*Chlamydia* antibodies in a test sample comprising the steps of:

- contacting a sample with the HMW protein of claim 1, the antigenic composition of claim 20 or the immunogenic composition of claim 19 to form, in the presence of said antibodies, *Chlamydia* antigen: anti-*Chlamydia* antibody immunocomplexes, and further,
- either detecting the presence of or measuring the amount of said immunocomplexes formed during step a) as an indication of the presence of said anti-*Chlamydia* antibodies in the test sample.

27. A diagnostic kit for detecting antibodies to *Chlamydia*, said kit comprising the HMW protein of claim 1, the antigenic composition of claim 20 or the immunogenic composition of claim 19, a container means for contacting
5 said protein or composition with a test sample suspected of having said antibodies and reagent means for detecting or measuring *Chlamydia* antigen: anti-*Chlamydia* antibody immunocomplexes formed between said protein or composition and said antibodies.

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28. A method for detecting the presence of *Chlamydia* in a test sample comprising the steps of:

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- a) contacting a test sample with the antibodies of claim 24 for a time sufficient to allow said antibodies to bind *Chlamydia*, if present, and to form a *Chlamydia*: anti-*Chlamydia* antibody immunocomplexes, and further,
- b) either detecting the presence of or measuring the amount of said immunocomplexes formed during step a) as an indication of the presence of said *Chlamydia* in the test sample.

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29. A diagnostic kit for detecting the presence of *Chlamydia*, said kit comprising the antibodies of claim 24,
25 container means for contacting said antibodies with a test sample suspected of having said *Chlamydia* and reagent means for detecting or measuring *Chlamydia*: anti-*Chlamydia* antibody immunocomplexes formed between said antibodies and said *Chlamydia*.

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30. A pharmaceutical composition comprising an effective amount of at least one component selected from the group consisting of:

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- a) a HMW protein, wherein the apparent molecular weight is about 105-115 kDa, as determined by SDS-PAGE, or a fragment or analogue thereof;

b) an isolated nucleic acid molecule encoding a HMW protein of a), or a fragment or analogue thereof;

5 c) an isolated nucleic acid molecule having the sequence of SEQ ID No.: 1, 23 or 24, the complimentary or degenerate sequence thereto or a nucleic acid sequence which hybridizes under stringent conditions thereto;

10 d) an isolated recombinant HMW protein or fragment or analogue thereof producible in a transformed host comprising an expression vector comprising a nucleic acid molecule as defined in b) or c) and expression means operatively coupled to the nucleic acid

15 molecule for expression by the host of said HMW protein or the fragment or analogue thereof;

e) a recombinant vector, comprising a nucleic acid sequence of b) or c) encoding a HMW

20 protein or fragment or analogue thereof;

f) a transformed cell comprising the vector of e), and

g) antibodies that specifically bind the component of a), b), c), d), e) or f),

25 and optionally a pharmaceutically acceptable carrier or diluent therefor.

31. A vaccine composition comprising an effective amount of at least one component selected from the group consisting of:

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- a) a HMW protein, wherein the apparent molecular weight is about 105-115 kDa, as determined by SDS-PAGE, or a fragment or analogue thereof;
 - b) an isolated nucleic acid molecule encoding a HMW protein of a) or a fragment or analogue thereof;

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a) an isolated nucleic acid molecule having the sequence of SEQ ID No.: 1, 23 or 24, the complimentary or degenerate sequence thereto or a nucleic acid sequence which hybridizes under stringent conditions thereto;

d) an isolated recombinant HMW protein or fragment or analogue thereof producible in a transformed host comprising an expression vector comprising a nucleic acid molecule as defined in b) or c) and expression means operatively coupled to the nucleic acid molecule for expression by the host of said HMW protein or the fragment or analogue thereof;

e) a recombinant vector, comprising a nucleic acid sequence of b) or c) encoding a HMW protein or fragment or analogue thereof;

f) a transformed cell comprising the vector of e), and

g) antibodies that specifically bind the component of a), b), c), d), e), or f),

and optionally an adjuvant, and a pharmaceutically acceptable carrier or diluent therefor, wherein the vaccine produces an immune response when administered to a host.

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32 A method of preventing, treating or ameliorating a disorder related to *Chlamydia* in a host in need of such treatment comprising administering to a host, an effective amount of the pharmaceutical composition of claim 30 or the vaccine composition of claim 31.

33. The method of claim 32, wherein the disorder is selected from the group consisting of a *Chlamydia* bacterial infection, conjunctivitis, urethritis, lymphogranuloma venereum (LGV), cervicitis, epididymitis, endometritis, pelvic inflammatory disease (PID), salpingitis,

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tubal occlusion, infertility, cervical cancer,
arteriosclerosis and atherosclerosis.

34. The method of claim 33 wherein the host is a
5 bird or a mammal.

35. The composition of any one of claims 19, 20,
30 or 31 formulated for *in vivo* administration to a host to
confer protection against disease caused by a species of
10 *Chlamydia*.

36. The composition of any one of claims 19, 20,
30, or 31 wherein the species is selected from the group
consisting of *Chlamydia trachomatis*, *Chlamydia pecorum*,
15 *Chlamydia psittaci* and *Chlamydia pneumoniae*.

37. The composition of any one of claims 19, 20,
30 or 31 formulated as a microparticle, capsule, or liposome
preparation.

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38. The protein of any one of claims 1, 4, 6, 16
and 17, wherein the protein binds to heparin or heparan-
sulfate.

39. The protein of any one of claims 1, 4, 6, 16
or 17, wherein the protein is an outer membrane protein.

40. A method for determining the presence of
nucleic acid encoding a HMW protein or a fragment or analogue
30 thereof in a sample, comprising the steps of:

a) contacting a sample with the nucleic acid
molecule of claim 7 or 10 or any fragment
thereof or complementary thereto to produce
duplexes comprising the nucleic acid molecule
and any said nucleic acid molecule encoding
35 the HMW protein in the sample and specifically
hybridizable therewith; and

b) determining the production of duplexes.

41. A diagnostic kit for determining the presence of nucleic acid encoding a HMW protein or fragment or 5 analogue thereof in a sample, comprising:

- a) the nucleic acid molecule of claim 7 or 10 or any fragment thereof or complementary thereto;
- b) means for contacting the nucleic acid with the sample to produce duplexes comprising the nucleic acid molecule and any said nucleic acid encoding the HMW protein in the sample and specifically hybridizable therewith; and
- c) means for determining the production of

duplexes.

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Add B4) Add D11

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